



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0400; FRL-9849-01-OCSP]

#### Picarbutrazox; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of picarbutrazox in or on multiple commodities which are identified and discussed later in this document.

Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0400, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0400 in the subject line on the first page

of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0400 by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of August 24, 2021 (83 FR 47275) (FRL-8792-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP #1F8917) by Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27410-8300. The petition

requested that 40 CFR 180.718(a) be amended by establishing tolerances for residues of the fungicide picarbutrazox, (1,1-dimethylethyl N-[6-[[[(Z)-[(1-methyl-1H-tetrazol-5-yl)phenylmethylene]amino]oxy]methyl]-2-pyridinyl]carbamate, in or on the following raw agricultural commodities: Barley, grain at 0.01 parts per million (ppm); Barley, hay at 0.01 ppm; Barley, straw at 0.01 ppm; Bean, forage at 0.01 ppm; Bean, hay at 0.01 ppm; Buckwheat, forage at 0.01 ppm; Buckwheat, grain at 0.01 ppm; Buckwheat, hay at 0.01 ppm; Buckwheat, straw at 0.01 ppm; Cotton at 0.01 ppm; Cotton, gin byproducts at 0.01 ppm; Cotton, undelinted seed at 0.01 ppm; Herb group 25 at 0.01 ppm; Millet, pearl, forage at 0.01 ppm; Millet, pearl, grain at 0.01 ppm; Millet, pearl, hay at 0.01 ppm; Millet, pearl, straw at 0.01 ppm; Millet, proso, forage at 0.01 ppm; Millet, proso, grain at 0.01 ppm; Millet, proso, hay at 0.01 ppm; Millet, proso, straw at 0.01 ppm; Oat, forage at 0.01 ppm; Oat, hay at 0.01 ppm; Oat, straw at 0.01 ppm; Oat, grain at 0.01 ppm; Pea, hay at 0.01 ppm; Pea, vines at 0.01 ppm; Rapeseed subgroup 20A at 0.01 ppm; Rye, forage at 0.01 ppm; Rye, grain at 0.01 ppm; Rye, hay at 0.01 ppm; Rye, straw at 0.01 ppm; Sorghum at 0.01 ppm; Spice group 26 at 0.01 ppm; Spinach at 0.01 ppm; Teosinte, forage at 0.01 ppm; Teosinte, grain at 0.01 ppm; Teosinte, hay at 0.01 ppm; Teosinte, straw at 0.01 ppm; Triticale, forage at 0.01 ppm; Triticale, grain at 0.01 ppm; Triticale, hay at 0.01 ppm; Triticale, straw at 0.01 ppm; Vegetable, *brassica*, head and stem, group 5-16 at 0.01 ppm; Vegetable, bulb, group 3-07 at 0.01 ppm; Vegetable, cucurbit, group 9 at 0.01 ppm; Vegetable, leafy, group 4-16, except spinach at 0.01 ppm; Vegetable, leaves of root and tuber, group 2 at 0.01 ppm; Vegetable, legume, group 6 at 0.01 ppm; Vegetable, fruiting, group 8-10 at 0.01 ppm; Vegetable, root and tuber, group 1, except potato at 0.01 ppm; Vegetable, stalk, stem, and leaf petiole group 22 at 0.01 ppm; Wheat, forage at 0.01 ppm; Wheat, grain at 0.01 ppm; Wheat, hay at 0.01 ppm; and Wheat, straw at 0.01 ppm. The August 24, 2021, notice of filing referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the

docket, <https://www.regulations.gov>. The only comment received on the notice of filing was from the U.S. Department of Agriculture, indicating support for the tolerance action.

Based upon review of the data supporting the petition, EPA is establishing tolerances in accordance with section 408(d)(4)(a)(i) of the FFDCA.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for picarbutrazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with picarbutrazox follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary

between tolerance rulemakings and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for picarbutrazox, most recently on March 5, 2021, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to picarbutrazox and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the March 5, 2021, rulemaking as described further in this rulemaking, as they remain unchanged.

#### *A. Toxicological Profile*

For a discussion of the Toxicological Profile of picarbutrazox, see Unit III.A. of the March 5, 2021, rulemaking (86 FR 12829) (FRL-10019-99).

#### *B. Toxicological Points of Departure/Levels of Concern*

For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the March 5, 2021, rulemaking.

#### *C. Exposure Assessment.*

Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the March 5, 2021, rulemaking.

*Dietary exposure from food and feed uses.* EPA's dietary exposure assessments have been updated to include the added exposure from the seed treatment uses of picarbutrazox on many agricultural commodities. In addition, the dietary exposure assessment was revised to reflect the updated Dietary Exposure Evaluation Model that incorporates the What We Eat in America (WWEIA) consumption data from 2005 –

2010. For the acute dietary exposure assessment, no toxicological effects of concern resulting from a 1-day or single exposure were identified; therefore, this assessment is unnecessary. For the chronic dietary exposure assessment, EPA used tolerance-level residues, 100 percent crop treated (PCT), and default processing factors.

*Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for picarbutrazox. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

*Drinking water, non-occupational, and cumulative exposures.* Drinking water exposures and residential (non-occupational) exposures are not impacted by the added seed treatment uses in this action. Since the last assessment in March 2021, the turf application rate has increased (from 0.33 lb picarbutrazox/acre to 0.44 lb picarbutrazox/acre), resulting in updated estimated drinking water concentrations (EDWCs). The most recent dietary risk assessment used the updated surface water EDWC of 2.33 ppb, which was calculated with the Pesticide in Water Calculator (PWC) ver. 2.001. Despite the increased turf application rate, the EDWC decreased from the March 2021 rule, which used a turf surface water EDWC of 2.56 ppb. The decreased EDWC is due to use of new weather data in the turf modeling scenario.

Picarbutrazox is currently registered for use on turf that could result in residential exposures. The residential risk estimate that was used in the aggregate assessment is incidental oral hand-to-mouth post-application exposure to treated turf/lawns for children aged 1 to less than 2 years old. The Agency would like to note that the March 2021 rule inaccurately described intermediate-term aggregate exposure. The only exposure, or risk assessed, for residential post-application exposures in the March 2021 rule was for incidental oral scenarios for children 1 to <2 years old, which is a short-term exposure. Intermediate-term exposure is not anticipated when assessing incidental oral exposures.

EPA's conclusions concerning cumulative risk remain unchanged from the March 5, 2021, rulemaking.

#### *D. Safety Factor for Infants and Children*

EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1x. See Unit III.D. of the March 5, 2021, rulemaking for a discussion of the Agency's rationale for that determination.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Picarbutrazox is not expected to pose an acute dietary risk, as no adverse effect from a single dose exposure was identified and no acute dietary endpoint was selected. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are <1% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure.

The Agency analyzed short-term aggregate risk by aggregating chronic dietary (food and drinking water) exposure to children 1 to <2 years old with incidental oral hand-to-mouth post-application exposure to children 1 to <2 years old on treated turf. EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 920 for children 1 to <2 years old. Because EPA's level of concern for picarbutrazox is an MOE of 30 or below, these MOEs are not of concern.



Based on the lack of chronic risk, EPA concludes that aggregate exposure to picarbutrazox will not pose a cancer risk to humans.

Therefore, based on these risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to picarbutrazox residues. More detailed information can be found at <https://www.regulations.gov> in the document titled “Picarbutrazox. Human Health Risk Assessment for the Proposed Section 3 Registration to Expand Seed Treatment Use for Several Agricultural Crops” in docket ID number EPA-HQ-OPP-2021-0400.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the March 5, 2021, rulemaking.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established an MRL for picarbutrazox.

##### *C. Revisions to Petitioned-For Tolerances*

EPA is establishing tolerances for three crop groups: (1) vegetable, foliage of legume, group 7; (2) grain, cereal, except rice, group 15; and (3) grain, cereal, forage, fodder and straw, group 16. EPA is not establishing tolerances for individual commodities included in the petition. For example, EPA is establishing a tolerance for grain, cereal, except rice, group 15 rather than establishing tolerances for the individual

commodities barley, grain; buckwheat, grain; oat, grain; pearl millet, grain; proso millet, grain; rye, grain; sorghum; teosinte, grain; triticale, grain; and wheat, grain.

EPA is not establishing a tolerance for cotton as requested because cotton is already established under the tolerance for cotton, undelinted seed. EPA is establishing tolerances for vegetable, root, subgroup 1A and vegetable, tuberous and corm, except potato, subgroup 1D rather than the petitioned-for tolerance for root and tuber vegetables, except potato, crop group 1. Because data on potato was not provided, EPA is establishing tolerances for subgroups 1A and 1D, which do not require potato representative commodity data. All commodities in group 1, except potato, are covered by establishing tolerances on those two subgroups, so EPA is establishing tolerances substantively consistent with what the petition requested.

EPA is also correcting the definitions of the following commodities to conform with EPA's Food and Feed Commodity Vocabulary. The commodity definition for herb crop group 25 is revised to herb group 25. The commodity definition for rapeseed (including canola) subgroup 20A is revised to rapeseed subgroup 20A. The commodity definition for spice crop group 26 is revised to spice group 26. The commodity definition for brassica head and stem vegetables crop group 5-16 is revised to vegetable, *Brassica*, head and stem, group 5-16. The commodity definition for bulb vegetable group crop group 3-07 is revised to vegetable, bulb, group 3-07. The commodity definition for cucurbit vegetables crop group 9 is revised to vegetable, cucurbit, group 9. The commodity definition for fruiting vegetables crop group 8-10 is revised to vegetable, fruiting, group 8-10. The commodity definition for leafy vegetables crop group 4-16 is revised to vegetable, leafy, group 4-16. The commodity definition for leaves of root and tuber vegetables crop group 2 is revised to vegetable, leaves of root and tuber, group 2. The commodity definitions for edible-podded legume vegetables crop subgroup 6A; succulent shelled pea and bean crop subgroup 6B; dried shelled pea and bean except

soybean, subgroup 6C are revised to vegetable, legume, group 6. The commodity definition for stalk, stem, and leaf petiole vegetable crop group 22 is revised to vegetable, stalk, stem, and leaf petiole, group 22.

Finally, EPA is removing the established tolerances of 0.01 ppm for corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover; soybean, forage; soybean, hay; and soybean, seed because these commodities are included in vegetable, legume, group 6; vegetable, foliage of legume, group 7; grain, cereal, except rice, group 15; or grain, cereal, forage, fodder, and straw, group 16.

## **V. Conclusion**

Therefore, tolerances are established for residues of picarbutrazox, (1,1-dimethylethyl N-[6-[[[(Z)-[(1-methyl-1H-tetrazol-5-yl)phenylmethylene]amino]oxy]methyl]-2-pyridinyl]carbamate, in or on cotton, gin byproducts at 0.01 ppm; cotton, undelinted seed at 0.01 ppm; grain, cereal, except rice, group 15 at 0.01 ppm; grain, cereal, forage, fodder, and straw, group 16 at 0.01 ppm; herb group 25 at 0.01 ppm; rapeseed subgroup 20A at 0.01 ppm; spice group 26 at 0.01 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 0.01 ppm; vegetable, bulb, group 3-07 at 0.01 ppm; vegetable, cucurbit, group 9 at 0.01 ppm; vegetable, foliage of legume, group 7 at 0.01 ppm; vegetable, fruiting, group 8-10 at 0.01 ppm; vegetable, leafy, group 4-16 at 0.01 ppm; vegetable, leaves of root and tuber, group 2 at 0.01 ppm; vegetable, legume, group 6 at 0.01 ppm; vegetable, stalk, stem, and leaf petiole group 22 at 0.01 ppm; vegetable, root, subgroup 1A at 0.01 ppm; and vegetable, tuberous and corm, except potato, subgroup 1D at 0.01 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 25, 2022.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180 -- TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.718, revise Table 1 to Paragraph (a) to read as follows:

**§ 180.718 Picarbutrazox; tolerances for residues.**

(a) \* \* \*

Table 1 to Paragraph (a)

Commodity	Parts per million
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Grain, cereal, except rice, group 15	0.01
Grain, cereal, forage, fodder, and straw, group 16	0.01
Herb group 25	0.01
Rapeseed subgroup 20A	0.01
Spice group 26	0.01
Vegetable, <i>Brassica</i> , head and stem, group 5-16	0.01
Vegetable, bulb, group 3-07	0.01
Vegetable, cucurbit, group 9	0.01
Vegetable, foliage of legume, group 7	0.01
Vegetable, fruiting, group 8-10	0.01
Vegetable, leafy, group 4-16	0.01
Vegetable, leaves of root and tuber, group 2	0.01
Vegetable, legume, group 6	0.01
Vegetable, stalk, stem, and leaf petiole group 22	0.01
Vegetable, root, subgroup 1A	0.01
Vegetable, tuberous and corm, except potato, subgroup 1D	0.01

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